OCT 25 2005

PATENT

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Ginger G. Grammer 10/25/05
Ginger G. Grammer Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Serial No.: | 09/764,630 |
| Filing Date: | January 18, 2001 |
| Applicants: | James H. Goethel, et al. |
| Title: | SYRINGE/PLUNGER COUPLING |
| Art Unit: | 3763 |
| Examiner: | Michael J. Hayes |
| Confirmation No.: | 8472 |
| Attorney Docket: | L-F 180DV |

Cincinnati, Ohio October 25, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION OF FRANK M. FAGO UNDER 37 C.F.R. § 1.132**

1) I am Frank M. Fago. I reside at 4508 Estate Court, Mason, Ohio 45040.

2) I received a B.A. degree in Manufacturing Engineering from Northern Kentucky University in 1995. I was a Design Engineer at Access Corporation from 1980-1989. From 1989 to the present I have been employed by Liebel-Flarsheim Company, the assignee of the present application. I am currently the Manager of Research and Development and oversee new product development, including injectors, syringes,

coupling mechanisms, etc. I am listed as an inventor or co-inventor on 25 patents, the majority of which are related to medical devices.

3) I have carefully reviewed and considered U.S. Patent Application Serial No. 09/764,630 ("the '630 application"), the Office Action dated July 26, 2005, issued in the '630 application, and U.S. Patent Nos. 3,747,479 ("Nightingale") and 4,677,980 ("Reilly") cited by the Examiner in that Office Action to support the rejection of the claims presented in the '630 application.

4) This Declaration is provided in order to illustrate the unique nature of the syringe/plunger coupling, which is the subject of the '630 application. The information provided herein should not in any way be construed as limitations of the apparatus or claims of the '630 application.

5) Nightingale is directed to a piston assembly that is used in syringes and stopcocks. Figure 7 of Nightingale is of a syringe including the piston assembly. As can be seen from Figure 7, a threaded sleeve (which the Examiner, in the July 26, 2005 Office Action, considers to be a "rearwardly-facing drive ram engaging coupling element") is coupled to an operating bar and mandrel to move the plunger within the syringe barrel. The operating bar and mandrel extend through the threaded sleeve. However, in my opinion, this operating bar and mandrel are not a drive ram, as would

be found on injectors such as those described in the present application. Further, a "drive ram engaging coupling element" would inherently require a "drive ram." Thus, since Nightingale does not disclose a drive ram, it cannot and does not, in my opinion, disclose a "drive ram engaging coupling element."

6) Further, referring to Fig. 7 of Nightingale, the knurled portion of the threaded sleeve is not adapted to be within an area enveloped by a coupling mechanism, in my opinion. First, there is no coupling mechanism disclosed by Nightingale that is designed to envelop the knurled portion of the threaded sleeve. Second, as is clear from Fig. 7, there is already a mechanism coupled to the extension in Nightingale: the operating bar and mandrel. If one were to envelop the knurled area of the threaded sleeve of Nightingale with any coupling mechanism, one would block off the opening that is used to receive the mandrel. In such a configuration, the operating bar and mandrel would no longer be useful and would have to be removed from Nightingale, thereby unnecessarily altering the apparatus of Nightingale.

7) Further, even if one were to assume that the extension of Nightingale could be enveloped with a coupling mechanism, the extension could not then be received within the barrel of the syringe shown in Fig. 7. This is because, in my opinion, the small clearance between the threaded sleeve and syringe barrel would not allow for any operative coupling mechanism to be placed therebetween. To place a coupling

mechanism within that space would require the mechanism to be so thin that it would not be able to achieve a gripping force to maintain any coupling between the mechanism and the threaded sleeve. Thus, to make the apparatus operative, Nightingale's extension would need to be lengthened so that at least a portion of the extension would remain outside the syringe barrel in all positions of the plunger. Otherwise, there would be no way to operatively envelop the threaded sleeve.

8) Reilly describes an angiographic injector that houses a syringe or syringes. A syringe plunger on each syringe is releasably connected to a drive mechanism. This connection can be facilitated by a component that extends from the rearward face of the syringe plunger.

9) In certain embodiments, the rearward facing extension of the present invention may include knurls to facilitate coupling between the extension and the coupling mechanism. These knurls can be a series of small ridges, and such knurls are disclosed in the present application, as can be seen at least at Figs. 4A-4C of the present application. These knurls provide friction to facilitate gripping between two surfaces (i.e., the extension and coupling mechanism), but do not form any interlocking engagement between the two surfaces.

10) In my opinion, Reilly does not show such knurls. Fig. 17 of Reilly, in particular, shows ridges or grooves that do interlockingly engage with a coupling mechanism. Referring to Fig. 17 and the disclosure at column 10, lines 4-31, the structures shown in Fig. 17 on the extension are a plurality of raised screw-type threads, which define a plurality of incline channels therebetween. The screw-type threads are designed to interact with a hook member, which is fixedly mounted on the right angle member of a hook assembly of the coupling mechanism (also shown in Figs. 18 and 19). In use, as the drive mechanism, including the coupling mechanism, is advanced by the drive piston, the hook-shaped members enter respective one of the channels between the screw threads. As this happens, the hook members pass through the channels. Eventually, the outer ends of the hook assemblies engage the extension on the plunger. In other words, the configuration of hooks on the coupling mechanism and threads on the extension engage to form an interlocking engagement to hold the syringe plunger to the drive ram.

11) I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further Declarant sayeth naught.

October 25th, 2005
Date

Frank M. Fago